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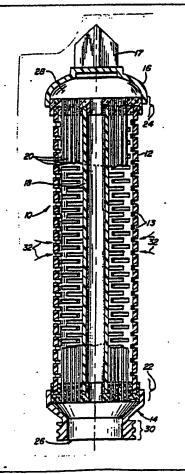
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(54) Title: FILTER

#### (57) Abstract

A filter (10) and a method of filtering fluids. In the filter (10), a plurality of porous, hollow fibers (20) surround a central tube (18) and are contained by a housing (12). The ends of the assembly are potted with a sealant to define first and second sealant-impregnated ends (22, 24) having open flow paths through the hollow fibers (20) and central tube (18) from one end to the other. A manifold (16) defining a typically closed chamber covers one end of the assembly and another manifold (14) covers the other end and defines a fluid portal (26) to the tube (18) and hollow fibers (20). Fluid may be filtered by passing it through the pores of the hollow fibers (20) from the outside to the inside and draining fluid from the portal (26). Alternatively, filtering of a fluid may be accomplished by introducing fluid through the portal (26) and passing it through the pores of the hollow fibers (20) from inside to out.



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#### FILTER

#### Field of the Invention

fically to filters for the filtration of medical fluids.

5 Particularly, the invention relates to microfilters used in the filtration of parenteral solutions during their manufacture. Porous, hollow fibers arranged in a cylindrical bundle generally comprise a permeating region to permeate fluid flowing from the exteriors of the fibers through porous, membrane walls to the interiors of the hollow fibers. Fluid can also be filtered by permeating fluid flowing from the interiors of the fibers through porous, membrane walls to the exteriors of the hollow fibers. The permeation is based on the principles of microfiltration.

#### Background of the Invention

Conventional, hollow fiber permeability apparatus... are extensively used in the medical field, for example in hemodialysis. Examples of hollow fiber permeability 20 apparatus used in hemodialysis are as follows: U.S. Patent 4,306,972, Dialysis Apparatus, to Denti, et al.; U.S. Patent 4,289,623, Hollow Fiber Dialysis, to Lee; U.S. Patent 4,219,426, Dialysis Device, to Spekle, et al.; U.S. Patent 4,212,744, Haemodialyzer Apparatus, to 25 Oota; U.S. Patent 4,202,776, Hollow-Fiber Permeability Apparatus, to Joh; U.S. Patent 4,187,180, Hollow-Fiber Permeability Apparatus, to Joh; U.S. Patent 4,201,673, Apparatus for Dialysis of Solution, to Kanno, et al.; U.S. Patent 4,031,012, Separatory Apparatus, to Gics; 30 and U.S. Patent 3,708,071, Hollow Fiber Membrane Device and Method of Fabricating Same, to Crowley. These hollow fiber apparatus have unidirectional blood flow through the hollow fibers from inlet to outlet. Microsolutes



and water are passed through the hollow fiber membrane. Differences in the concentration of ions on each side of the membrane allow the desired ions to be drawn from the blood.

- Hollow fiber membrane technology is also used in apparatus commonly known as artificial lungs. In artificial lungs, oxygen and carbon dioxide are exchanged with each other to increase blood oxygen content. Reverse osmosis apparatus also employ the technology of permeable hollow fibers. These apparatus are used in purification or desalination of water where the membrane retains virtually all ions and passes water. Examples of hollow fibers particularly adapted for use in reverse osmosis are found in the following references: U.S.
- Patent 4,084,036, Asymmetric Hollow Acrylic Fibers, to Leonard; U.S. Patent 3,953,334, Fluid Fractionating Apparatus, to Brun, et al.; and U.S. Patent 3,930,105, Hollow Fibres, to Cristen, et al.
- Porous, hollow fibers are used in a wide variety

  20 of permeability and filter applications because of a
  basic advantage over flat membranes. Available surface
  area is increased by choosing porous, hollow fibers
  thereby reducing space requirements for permeability
  apparatus.
- Hollow fiber filters have been constructed with one end of a hollow fiber bundle closed. During filtration using a sealed end filter, fluid flows into the unsealed ends and is filtered across the membrane of the porous, hollow fibers. Alternatively, filtrate can flow across the membrane of the porous, hollow fibers and exit through the single open end area. Fluid filtered at the end farthest from the main flow stream has to flow through the entire length of fiber in either alternative. This reduces the efficiency of



the filter. A large percentage of the pressure differential is used to move fluid within the hollow fibers rather than across the membrane of the hollow fibers for filtration. Consequently, pressure differentials are high and flow rates are low.

A filter can also be constructed by bending the open ends of the bundle of fibers back on themselves in a generally "U"-shaped configuration, and feeding into both ends. For example, see U.S. Patent 4,075,100, 10 Dialysis Unit and Dialysis Apparatus Employing the Dialysis Unit, to Furuta, et al. and U.S. Patent 4,025,436, Liquid Treatment Apparatus, to Tsuda, et al. Other difficulties must be addressed where generally "U"-shaped configuration filters are used. When the hollow fibers 15 are bent in a "U" shape, hollow fibers close to the smaller, inner radius of the "U" can be pinched shut. Hollow fibers close to the larger, outer radius are under tension and can be flattened shut. Compromising the arc of the "U" bend to avoid these problems also compromises 20 the overall size of the filter. Furthermore, a shorter and stouter "U"-shaped device is more cumbersome to pot and its transverse dimension is inconveniently large.

It is desirable to provide a microfilter where the pressure differential across the filter membrane can be lowered and where the filtrate flow rate is increased, thereby increasing the overall efficiency of the microfilter. Furthermore, the disadvantages encountered in the manufacture of a "U"-shaped filter, namely pinched shut and flattened shut hollow fibers, and potting difficulties, would desirably be avoided without compromising the size of the filter or the ease of manufacture. Important, too, is the adaptability of a more efficient filter for use in presently existing industrial hardware. It would also be desirable to provide a microfilter where small leaks in the filter membrane can be repaired without discarding the entire filter.



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### Brief Summary of the Invention

The present invention provides a microfilter having particular utility in the filtration of parenteral solutions during their manufacture, as well as any other desired uses. The filter includes a non-permeable central tube having open ends. Porous, hollow fibers, typically in axial alignment with the central tube, are potted with a sealant to define first and second sealant-impregnated ends. Conventional methods of impregnating the ends of a bundle of hollow fibers may be employed particularly by using hollow fiber dialyzer technology. One method of potting hollow fibers is disclosed in U.S. Patent 4,227,295, Method of Potting the Ends of a Bundle of Hollow Fibers Positioned in a Casing, to Bodnar, et al.

It should be understood that the porous, hollow fibers are not restricted to axial alignment with the tube. That is, the fibers are in longitudinal relation with the tube where "longitudinal relation" contemplates, for example, a helical arrangement of fibers, or any other arrangement in which the overall direction of the fibers is longitudinal. Furthermore, the filter of this invention is not restricted to having a non-permeable, central tube. In some filtering situations a permeable tube may be used, and the positioning of the tube is not absolutely restricted to a central location with respect to the general filter geometry.

After potting or sealant-impregnating, the ends are cut so that the hollow fibers and the tube have open flow paths from the first end to the second end. A casing or housing is used to contain the central tube and the hollow fibers, as well as to assist in the potting of the ends. The housing of this invention for dead end filtration is perforated to allow fluid flow into or out of the housing. One end of the filter is covered by a



30

manifold defining a closed chamber thereover which communicates with one end of the central tube and hollow fibers. A manifold which defines a fluid portal covers the other end of the filter, and communicates with the other end of the central tube and hollow fibers. Thus the non-permeable central tube shunts fluid between the fluid portal and the closed chamber. This design is particularly suited for dead-end microfiltration applications.

Another embodiment of this invention contemplates 10 use in cross-flow microfiltration applications. again, conventional potting techniques are used to pot the porous, hollow fibers and the central tube within an enclosed, non-perforated housing. The defined first 15 and second potted ends are cut so that the hollow fibers and the tube have open flow paths from the first end to the second end. Inlet and outlet connections, located at opposite ends of the housing, define a closed flow path over the outside of the fibers. One end of the filter is covered by a manifold defining a closed chamber thereover which communicates with one end of the central tube and hollow fibers. A manifold which defines a fluid portal covers the other end of the filter, and communicates with the other end of the central tube and hollow fibers. In this filter embodiment, fluid flows across the hollow fibers from the inlet connection to the outlet connection. Fluid is filtered through the porous, hollow fibers from the exterior to the interior and is collected from the fluid portal end.

Advantages of the present invention over existing microfilters are numerous. By allowing fluid to flow through both ends of the hollow fibers, a 40 to 100 percent increase in performance of the filter can be realized over sealed end filters. Known hollow fiber



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dialyzer technology can easily be used to manufacture the filters. Filters of the present design can be placed in existing industrial hardware, thereby obviating costly changeover. Repair of a leaky filter 5 can be made simply by identifying the leaky fibers and sealing the ends; thus this filter is repairable.

An alternative embodiment for cross-flow microfiltration applications minimizes the number of external connections for this type filter while maximizing 10 efficiency of the filter.



## Brief Description of the Drawings

For a more complete understanding of this invention, reference should now be had to the embodiments illustrated in greater detail in the accompanying drawings.

5 In the drawings:

Figure 1 is a perspective view of the filter of the present invention.

Figure 2 is a cross-section of the filter taken along line 2-2 of Figure 1, showing the central tube and 10 manifolds covering the ends.

Figure 3 is a cross-section of the filter taken along line 3-3 of Figure 1, showing the arrangement of porous, hollow fibers in the filter.

Figure 4 is a cross-section, similar to Figure 3, showing another arrangement of porous, hollow fibers in the filter.

Figure 5 is a cross section, similar to Figure 3, showing still another arrangement of porous, hollow fibers in the filter.

20 Figure 6 is a cross-section of the filter of the present invention for use in cross-flow microfiltration applications.



## Description of the Preferred Embodiments

The basic configuration of the filter of the present invention is illustrated in the perspective view shown in Figure 1. Filter 10 is shown with cylindrical housing 12 having perforations 13. The perforations generally can be in any arrangement or of any shape.

Lower manifold 14 and upper manifold 16 cover the ends of the filter. Housing 12 may be of generally conventional design, and may be proportioned to fit presently existing filter systems, for upgrading the system performance with little or no "hardware" modification.

The construction of filter 10 of the present invention is better appreciated by viewing the perspective view of Figure 2. Cylindrical housing 12 is shown enclosing central, non-permeable tube 18 and a plurality of porous, hollow fibers 20. The assembly of porous, hollow fibers 20 and central tube 18 has first sealant-impregnated end 22 and second sealant-impregnated end 24. First end 22 and second end 24 may be potted using conventional potting materials such as polyurethane, and following conventional methods of potting hollow fiber assemblies. After the ends have been potted they are cut to define open flow paths from first end 22 to second end 24.

Lower manifold 14, having fluid portal 26, covers first end 22. Upper manifold 16 covers second end 24 to define closed chamber 28 enclosing second end 24.

The filter of the present invention may be used in either of two manners. In preferred use, filter 10 is placed in a chamber containing the fluid to be filtered. End 30 of lower manifold 14 is generally attached to a fixture which allows fluid passage out of filter 10. Tip 17 is placed in a fixture to generally stabilize filter 10.



Fluid 32 is shown entering perforations 13 of housing 12. Fluid 32 is filtered through the walls of porous, hollow fibers 20 into the bores thereof, and simultaneously flows toward first end 22 and second end 24. Fluid exiting the porous, hollow fibers at second end 24 enters closed chamber 28 for shunting through central tube 18 to lower manifold 14. Filtered fluid exiting from porous, hollow fibers 20 at first end 22 and shunted fluid exiting from central tube 18 flow together out of portal 26 of lower manifold 14 for collection.

Filtration is preferred from outside to inside for a number of reasons. For instance, the outsides of hollow fibers have a larger surface area than the inside, and thus provide a larger membrane surface for filtering, thus increasing filter efficiency. Also, when filtering from outside to inside, hollow fibers will collapse if pressures are too great. Thus, unfiltered fluid will not pass through for collection. However, when filtering is from inside to outside, fibers can burst if pressures are too great, thus contaminating the filtered fluid.

It should also be appreciated that at lower pressures though, fluid can be filtered by passing it through the filter of the present invention in the opposite direction. That is, fluid can pass from inside the fibers to the outside. Fluid enters portal 26 of lower manifold 14. A portion of the fluid is shunted through central tube 18 while the unshunted portion of fluid enters porous, hollow fibers 20 at first end 22. The shunted fluid fills closed chamber 28, from where fluid enters porous, hollow fibers 20 at second end 24. Fluid entering both ends of porous, hollow fibers 20 is filtered through the pores of the hollow fibers and percolates through perforations 13 in housing 12.



It can be appreciated that housing 12 supports, protects and contains the assembly of porous, hollow fibers and the central tube during the potting process and during filtration.

- Allowing flow through both ends of the porous, hollow fibers achieves approximately a 40 to 100 percent increase in filtering efficiency over a sealed-end filter irrespective of whether fluid is filtered from outside to inside or from inside to outside.
- Figure 3 shows the arrangement of porous, hollow fibers 20 surrounding central tube 18. Alternatively, hollow fibers 20a, shown in Figure 4, are arranged in bundles separated by radial ribs 34. Figure 5 shows another alternative arrangement of porous, hollow fibers 20b. Porous, hollow fibers 20b are shown contained in a screen matrix or fabric. The screen matrix may then be wound around central tube 18b.

Figure 6 illustrates the construction of filter 40, another embodiment of the present invention, suitable for cross-flow microfiltration applications. Filter 40 is shown with housing 42. Housing 42 may be of a design generally conventional for tubular housings used for hollow fiber dialyzers. An example of a cylindrical, tubular housing for a hollow fiber dialyzer is disclosed in U.S. Patent 4,227,295, supra.

Housing 42 is shown enclosing central, non-permeable tube 44 and a plurality of porous, hollow fibers 46. The assembly of porous, hollow fibers 46 and central tube 44 have first sealant-impregnated end 48 and second sealant-impregnated end 50. First end 48 and second end 50 may be potted using conventional potting materials such as polyurethane, and following conventional methods of potting hollow fiber assemblies. After the ends have been potted they are cut to define



open flow paths from first end 48 to second end 50.

Lower manifold 52, having fluid portal 56, covers first end 48. Upper manifold 54 covers second end 50 to define closed chamber 58 enclosing second end 50.

Inlet connection 60 and outlet connection 62 are located at the respective ends of filter 40. It should be realized that the location of the inlet and outlet connections on the respective ends of the filter is

not restricted to the positions shown in the figure.

10 Inlet connection 60 and outlet connection 62 function to define a cross-flow path for fluid over hollow, porous filters 46.

In preferred use, a feed line is connected to inlet connection 60 and a collection line is connected 15 to outlet connection 62. Fluid flows over the outsides of porous, hollow fibers 46 for filtering to the inside. Sealant 64 functions to separate filtered from unfiltered fluid. End 66 of lower manifold 52 is generally attached to a fixture which allows fluid passage out 20 of filter 40. Fluid 68 is shown entering inlet connection 60 of housing 42. Fluid 68 is filtered through the walls of porous, hollow fibers 46 into the bores thereof, and simultaneously flows toward first end 48 and second end 50. Fluid exiting the porous, hollow 25 fibers at second end 50 enters closed chamber 58 for shunting through central tube 44 to lower manifold 52. Filtered fluid exiting from porous, hollow fibers 46 at first end 48 and shunted fluid exiting from central tube 44 flow together out of portal 56 of lower mani-30 fold 52 for collection.

Many benefits are realized by using cross-flow filtration techniques. Cross-flow filtration extends the life of filters because large quantities of particles do not build up on the filter membrane as occurs



with dead-end filters. Particles are substantially washed away by the flowing, unfiltered fluid in cross-flow filters. The particles that are deposited on the filter membrane can be washed away by using generally known methods of back flushing cross-flow filters, further extending their useful life. These back flushing methods generally are not adaptable to dead end filters.

Gelatinous solutions can be filtered with crossflow filters. It is difficult, if not impossible, to

10 filter gelatinous solutions with dead-end filters. Indeed, by using the cross-flow filter embodiment of this
invention gelatinous solutions can be filtered at relatively high shear velocities and relatively low flow
rates. This is possible because the porous, hollow

15 fibers -- as compared with a flat membrane -- provide
more membrane surface area for a given quantity of
membrane material.

The arrangement of porous, hollow fibers 46 may generally be the arrangement shown in Figure 3 with the porous, hollow fibers surrounding the central tube. Alternatively, the hollow fibers may be arranged in bundles separated by radial ribs as shown in Figure 4, or the porous, hollow fibers may be contained in a screen matrix or fabric which is then wound around the central tube as shown in Figure 5.

Polypropylene, polyolefins with a high polypropylene content, polyethylene, or nylon are preferred materials for the hollow fiber membranes used in the present invention. It should be understood, however, that many other thermoplastic resins are also suitable materials for hollow fiber, microporous membranes usable in this invention. Porous, hollow fibers 20 or 46 used in this invention may typically have an inside



diameter of between 100 and 500 microns. Wall thickness of the fibers will typically range from 50 to 300 microns. The void fraction, that is the ratio of the difference between the density of the membrane material and the density of the membrane to the density of the membrane material represented as a percentage, of the hollow fibers typically ranges from 60 to 75 percent. Average pore size preferably is between 0.1 and 0.5 microns. Good filtration rates have been achieved using polypropylene hollow fibers having inside diameters of 320 microns, wall thickness of 150 microns and void fractions of 65 percent.

Hollow fiber pore sizes for dead end and crossflow microfiltration applications typically are about

15 0.4 micron for filtration of pharmaceuticals, 0.2 micron
for sterilizing of fluids, and from 0.05 to 0.1 micron
for filtering washing fluids used in the electronics
industry.

The above has been offered for illustrative purposes 20 and is not intended to limit the invention of this application, which is defined in the claims below.



#### WHAT IS CLAIMED IS:

- A hollow fiber filter comprising:
- a tube having open ends;
- a plurality of porous, hollow fibers in longitudi5 nal relation with said tube, and potted with a sealant
  to define first and second sealant-impregnated ends,
  said hollow fibers and said tube having open flow paths
  therethrough from the first end to the second end;

an upper manifold covering the second end; and,

- a lower manifold surrounding the first end and defining a fluid portal to said tube and hollow fibers.
  - 2. The filter of Claim 1 wherein said hollow fibers radially surround said tube and are generally parallel with said tube.
- 15 3. The filter of Claim 1 further comprising a perforated housing extending between the first and second ends containing said tube and porous, hollow fibers.
  - 4. The filter of Claim 1 wherein separate bundles of porous, hollow fibers surround said tube.
- 5. The filter of Claim 1 wherein the material of said porous, hollow fibers is selected from the group consisting of polypropylene, polyethylene and nylon.
  - 6. A hollow fiber filter comprising:
  - a central tube having open ends;
- a plurality of porous, hollow fibers radially surrounding said central tube and generally longitudinally
  aligned with said central tube and potted with a sealant
  to define first and second sealant-impregnated ends, said
  hollow fibers and said tube having open flow paths therethrough from the first end to the second end;
  - a tubular, perforated housing surrounding said central tube and extending between the first and second ends for containing said tube and said porous, hollow fibers;
- an upper manifold covering the second end to define 35 a closed chamber over the second end; and,



- a lower manifold covering the first end to define a fluid portal to said tube and hollow fibers.
- 7. The filter of Claim 6 wherein separate bundles of porous, hollow fibers surround said central tube.
- 8. The filter of Claim 6 wherein the material of said porous, hollow fibers is selected from the group consisting of polypropylene, polyethylene and nylon.
  - 9. A hollow fiber filter comprising:
  - a central, non-permeable tube having open ends;
- a plurality of porous, hollow fibers surrounding said central tube and generally longitudinally aligned with said central tube and potted with sealant to define first and second sealant-impregnated ends, said hollow fibers being contained by a screen matrix, said hollow fibers and said tube having open flow paths therethrough from the first end to the second end;
  - a perforated housing surrounding said tube and extending between the first and second ends containing said tube and said porous, hollow fibers;
- an upper manifold covering the second end to define a chamber over the second end; and,
  - a lower manifold covering the first end to define a fluid portal to said tube and hollow fibers.
  - 10. The filter of Claim 9 wherein said perforated housing is cylindrical and concentric with said tube.
    - 11. The filter of Claim 9 wherein the material of said porous, hollow fibers is selected from the group consisting of polypropylene, polyethylene and nylon.
- 12. The filter of Claim 10 wherein the material of said porous, hollow fibers is selected from the group consisting of polypropylene, polyethylene and nylon.
  - 13. The filter of Claim 11 wherein said fibers have a pore size between 0.1 and 5 microns, an inside



end:

diameter of between 100 and 500 microns, a wall thickness of between 50 and 300 microns and a void fraction of between 60 and 75 percent.

- 14. A hollow fiber filter for cross-flow filter
  5 applications comprising:
  - a tube having open ends;
  - a plurality of porous, hollow fibers in longitudinal relation with said tube, and potted with a sealant to define first and second sealant-impregnated ends,
- 10 said hollow fibers and said tube having open flow paths therethrough from the first end to the second end;
- a tubular housing surrounding said tube and extending between the first and second ends containing said
  tube and said porous, hollow fibers, said housing having
  an inlet connection and an outlet connection which define a flow path over the outside of said hollow fibers
  separate from the defined flow path through said hollow
  fibers and said tube from the first end to the second
- an upper manifold covering the second end to define a closed chamber over the second end; and,
  - a lower manifold covering the first end to define a fluid portal to said tube and hollow fibers.
- 15. The filter of Claim 14 wherein said hollow
  25 fibers radially surround said tube and are generally parallel with said tube.
  - 16. The filter of Claim 14 wherein separate bundles of porous, hollow fibers surround said tube.
- 17. The filter of Claim 14 wherein said tube is a central, cylindrical, non-permeable tube; said fibers radially surround said central tube and are generally parallel with said central tube; and said tubular housing is cylindrical and non-permeable.



- 18. The filter of Claim 17 wherein separate bundles of porous, hollow fibers surround said central tube.
- 19. The filter of Claim 17 wherein the material 5 of said porous, hollow fibers is selected from the group consisting of polypropylene, polyethylene and nylon.
- 20. The filter of Claim 17 wherein said fibers have a pore size between 0.1 and 5 microns, an inside diameter of between 100 and 500 microns, a wall thickness of between 50 and 300 microns and a void fraction of between 60 and 75 percent.
  - 21. A fluid filtration method comprising the steps of:

passing a fluid through a fluid portal;

introducing the fluid to a first end of a filtration system, said filtration system comprised of a central tube having open ends and a plurality of porous, hollow fibers surrounding the central tube and potted with a sealant to define first and second sealant-impregnated ends, said hollow fibers and said tube having open flow paths therethrough from the first end to the second end;

shunting a portion of fluid at the first end through the central tube to a closed chamber over the second end;

feeding an unshunted portion of fluid to the first

25 end;

feeding the shunted portion of fluid to the second end; and,

simultaneously passing fluid through the first and second ends of the hollow fibers, whereby fluid is fil30 tered through the pores of the hollow fibers from the interior of the fibers to the exterior of the fibers.

22. A fluid filtration method comprising the steps of:



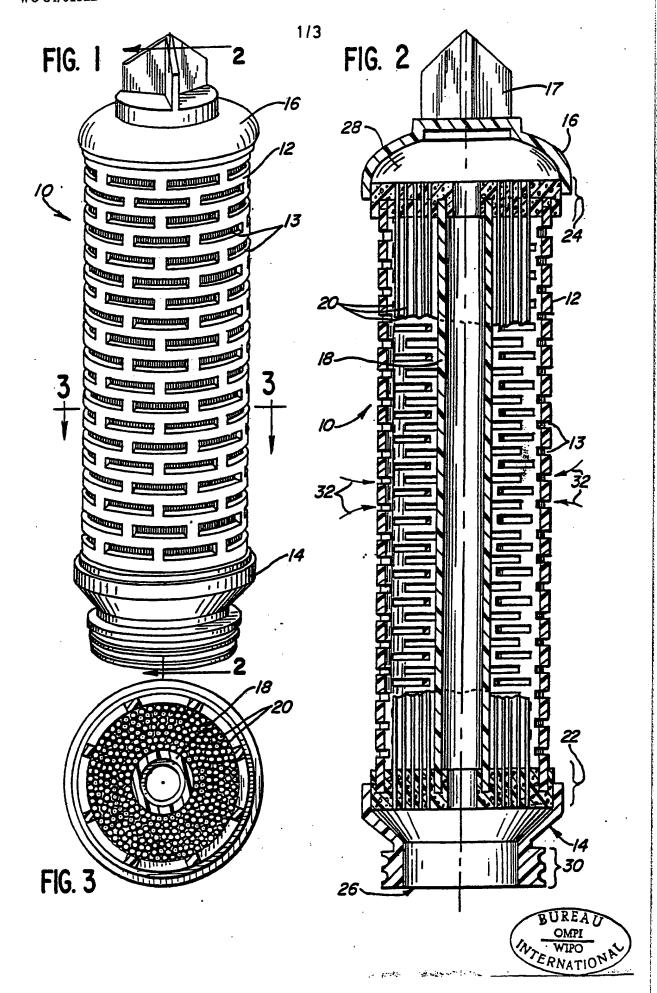
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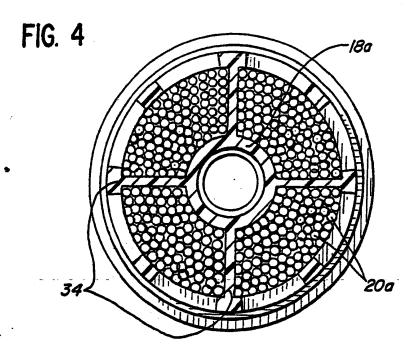
filtering fluid through the pores of hollow fibers from the exterior of the fibers to the interior of the fibers, said filtration system comprised of a central tube having open ends and a plurality of porous, hollow fibers surrounding the central tube and potted with a sealant to define first and second sealant-impregnated ends, said hollow fibers and said tube having open flow paths therethrough from the first end to the second end, said second end covered by a manifold to define a closed chamber thereover:

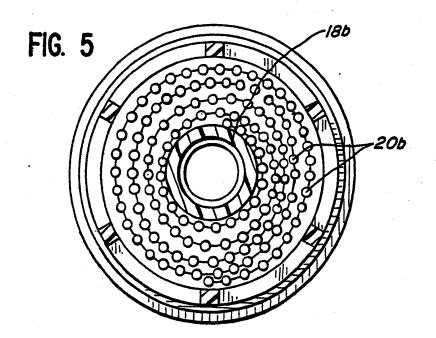
draining filtered fluid from the hollow fibers at first end and the covered, second end of the filter, and passing fluid from the second end through the central tube to combine with fluid drained from the first end; and

passing the combined fluids through a fluid portal at the first end out of the filter.

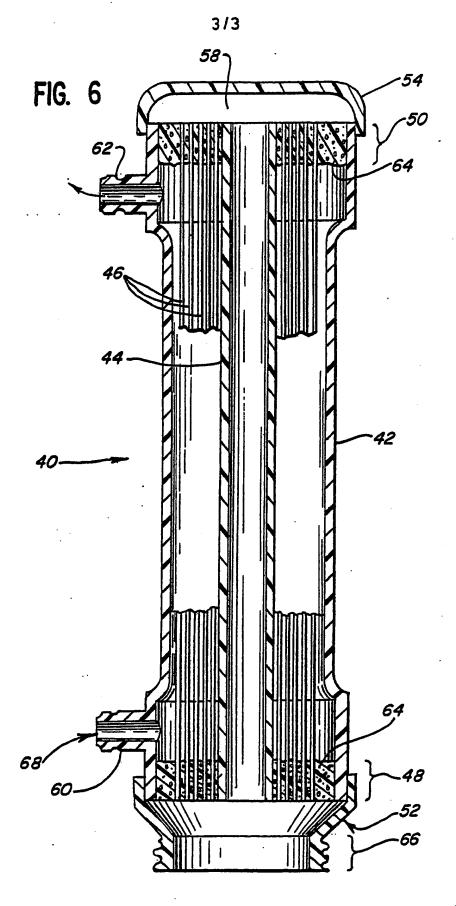














#### INTERNATIONAL SEARCH REPORT

International Application No PCT/US83/01340

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I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) 3										
According to International Patent Classification (IPC) or to both National Classification and IPC U.S. C1.										
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IV. CERTIFICATION										
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